Attorney Docket No.: RU-0191

Inventors: Allan H. Conney

Serial No.: 10/657,685

Filing Date: September 8, 2003

Examiner: Not Yet Assigned

Group Art Unit: 1614

Title: Compositions and Methods for Inhibiting

Proliferation in Human Prostate Cancer

Cells

I, Jane Massey Licata, Registration No. 32,257, certify that this correspondence is being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to the Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450

On this date: February 5, 2004

Jane Massey Licata, Registration No. 32,257

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

## INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

(XX) In accordance with §1.97(b), since this Information

Disclosure Statement is being filed either within three

months of the filing date of the above-identified

application, within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, no additional fee is required.

- ( ) In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, therefore:
  - ( ) Certification in Accordance with §1.97(e) is attached hereto: or
  - ( ) The fee of \$180.00 as set forth in \$1.17(p) is attached.
- ( ) In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee, therefore included are: Certification in Accordance with §1.97(e); Petition Requesting Consideration of the Information Disclosure Statement; and the fee of \$130.00 as set forth in §1.17(I)(1).
- (XX) Copies of each of the references listed on the attached Form PTO-1449 (modified) are enclosed herewith.

( ) In accordance with §1.98(d), copies of some or all of the references listed on the attached Form PTO-1449 (modified) are not enclosed herewith because they were previously submitted to the U.S. Patent and Trademark Office in prior application Serial No. \_\_\_\_\_\_, filed \_\_\_\_\_\_, for which a claim for priority under 35 U.S.C. §120 has been made in the instant application.

Please charge any deficiency or credit any overpayment to Deposit Account No. 50-1619. This form is submitted in duplicate.

- ( ) The relevance of the listed references in a foreign language is as stated in the specification at pages @@.
- (XX) All listed references are in the English language.

Respectfully submitted,

Janasycera

Jane Massey Licata
Registration No. 32,257

Date: February 5, 2004

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## Form PTO-1449 Modified

List of Patents and Publications
Cited by Applicant
(Use several sheets if necessary)

U.S. Department of Commerce

Applicant

Allan H. Conney

Filing Date Group September 8, 2003 1614

AA	Chen et al., "Pharmacokinetics and efficacy of low-dose all-trans retinoic acid in the treatment of acute promyelocytic leukemia", Leukemia 1996 10:825-828
AB	Blagosklonny et al., "Defects in p21WARF1/CIP1, Rb, and c-myc Signaling in Phorbol Ester-resistant Cancer Cells", Cancer Research 1997 57:320-325
AC	Cui et al., "A Sensitive Bioassay for Measuring Blood Levels of 12- O-Tetradecanoylphorbol-13-acetate (TPA) in Patients:Preliminary Pharmacokinetic Studies", Oncology 2002 13:169-174
AD	Coster et al., "Experimental Studies with Liarozole (R75 251): an Antitumoral Agent which Inhibits Retinoic Acid Breakdown", J. Steroid Biochem. Molec. Biol. 1992 43(1-3):197-201
AE	Garzotto et al., "12-0-Tetradecanoylphorbol-13-acetate- induced Apoptosis in LNCaP Cells Is Mediated through Ceramide Synthase1 <sup>1</sup> ", Cancer Research 1998 58:2260-2264
AF	Garzotto et al., "Reversal of Radiation Resistance in LNCaP Cells by Targeting Apoptosis through Ceramide Synthase1", Cancer Research 1999 59:5194-5201
AG	Han et al., "Effect of intravenous infusions of 12-0-tetradecanoylphorbol-13-acetate (TPA) in patents with myelocytic leukemia:Preliminary studies on therapeutic efficacy and toxicity", Proc. Natl. Acad. Sci. USA 1998 95:5357-5361
АН	Han et al., "12-0-Tetradecanoylphorbol-13-acetate (TPA)-induced increase in depressed white blood cell counts in patients treated with cytotoxic cancer chemotherapeutic drugs", Proc. Natl. Acad. Sci. USA 1998 95:5362-5365
AI	Konno et al., "Growth Control of Human Prostatic Cancer Cells by the Phorbol Ester TPA:Possible Involvement of Protein Kinases", Anticancer Research 1996 16:1843-1850

**EXAMINER** 

DATE CONSIDERED

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## Docket No. Serial No. Form PTO-1449 Modified RU-0191 10/657,685 List of Patents and Publications Applicant Cited by Applicant Allan H. Conney (Use several sheets if necessary) Filing Date Group U.S. Department of Commerce September 8, 2003 1614 OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Laska et al., "Simple Designs and model-free Tests for ΑJ Synergy", Biometrics 1994 50:834-841 Powell et al., "Persistent Membrane Translocation of Protein Kinase C $\alpha$ AΚ during 12-0-Tetradecanoylphorbol-13-acetate-induced Apoptosis of LNCaP Human Prostate Cancer Cells1", Cell Growth and Differentiation 1996 7:419-428 Phase Strair et al., "Administration of a Phorbol Ester to Patients with ALHematological Malignancies: Prelminary Results from a I Clinical Trial of 12-O-Tetradecanoylphorbol-13-acetate", Clinical Cancer Research 2002 8:2512-2518 Zheng et al., "Synergistic Effects of Clinically Achievable Concentrations AM of 12-O-Tetradecanoylphorbol-13-acetate in Combination With all-trans Retinoic Acid, $1\alpha$ , 25-Dihydroxyvitamin $D^3$ , and Sodium Butyrate on

DATE CONSIDERED

**EXAMINER**